National Children's Study
National Association of County Officials Conference Call
December 15, 2004

OPERATOR: I would now like to introduce your host for today's conference call, Ms. Chris Shreeve. You may proceed.

MS. SHREEVE: Thank you.

Good afternoon, and good morning to those of you who are joining us from the West Coast. My name is Chris Shreeve, and I'd like to welcome you here today on behalf of the National Children's Study. Today's call is the first of two calls the National Children's Study Program Office is holding this week with participating counties. There's a call tomorrow; it will be at the same time, with the same call-in number, with health officials from your counties. If there are any health officials on today's call, you're invited to stay on the line and stay with us. For those of you from your counties, if there are other health officials that you know of in your offices who you think would like to participate on tomorrow's call, please let them know.

Just a few details before I introduce today's speakers. First, as you heard from the operator when you called in, if you're having any difficulty with your line, you want to press *0. And at the end of the remarks today, we will open up the forum for your questions. To ask a question, you press 1 and an operator will tell you what to do.

Second, today's session will be recorded and a transcript may be posted to the National Children's Study Web site. We just wanted to let you know that.

Finally, the National Children's Study Program Office sent you a FedEx packet of background materials on the Study last month. I know that not all of you received those. They were signed for by someone in your office. However, if you didn't receive that packet, you can find the same information on the Web site at www.nationalchildrens study.gov. And don't worry, we'll be giving you other ways to get in touch with us at the end of this call.

Now I'd like to introduce today's speakers from the National Children's Study Program Office. First, we're going to be hearing from Dr. Peter Scheidt. He's the program director for the National Children's Study. He'll give you an introduction to the Study today and talk to you about its goals and its benefits. He'll be followed by Jim Quackenboss, who will be joining us. He's an environmental scientist. He'll be speaking next on how the Study locations were chosen. And finally, Sarah Keim, Study coordinator from the Program Office, will tell you about the timeline for the Study and how your particular county may get involved.

Each speaker will be speaking for about 5 minutes, and then we'll open up the call to questions from you. Thank you very much for coming today. Dr. Scheidt.

DR. SCHEIDT: Yes, hello. Thank you very much for joining us. I'm glad to be able to share information about the National Children's Study.

The most important part of this call is to have an opportunity to answer your questions. So I'll give the very briefest summary that will try to anticipate a few of the questions that you might have.

As you may be aware, the National Children's Study goal is to pinpoint the causes of many of today's childhood diseases and disorders and to provide researchers and health care providers who work with children with a resource of data and information to develop prevention strategies to improve the health and safety of our children.

One of the most frequent questions that I'm asked is, how did this begin and why did it start? It began with a task force appointed by the President of seven cabinet offices in the late 1990s that was charged with proposing strategies to reduce the risks of environmental exposures, a broad range of environmental exposures that were known and for which there were concerns, and how to reduce those and improve our children's health. This task force has continued through the current administration and has been reappointed twice, so it spans the past about 6 years of both administrations.

The task force realized that it could not provide these answers because the information was simply not available and, in order to do so, a program of research would be necessary to provide the clear answers and direction for how to respond to the potential concerns about environmental exposures and the ways in which a number of important health problems may be influenced by various environmental exposures. Therefore, a group of health agencies led by the National Institute of Child Health and Human Development began the planning of this study with several other agencies, the EPA and the CDC, and the National Institute of Environmental Health Sciences.

The [plan for the] Study, as laid out in the planning process and now planned, is that it be a longitudinal study of children in their families and their environments, that it be national in scope with a number of important hypotheses to improve the health of children, that environment is very broadly defined, and measures will include measures of chemical, physical, behavioral, and social and cultural exposures, that it would be large enough to answer important questions, and that there'd be about 100,000 children. So that's the plan—to follow from early pregnancy, 100,000 women, and then their children from the pregnancy, through to adulthood.

So it's a very ambitious study, beginning in pregnancy and concluding in adulthood. [The plan is] that it includes genetic information and state-of-the-art technology and that it be carried out with the many agencies of the federal government that are involved with it, and partners from the private sector, around the country, both industry advocacy groups and states and counties with partners in this study.

The measures that will be included as part of the Study are to include biological, chemical, physical and psychosocial exposures, which will be measured and tracked against, through pregnancy, birth outcomes and stages of child development, and measuring the conditions in the development of children through these subsequent stages.

Data from the Study locations across the country will be compiled and reported on a national basis. Counties will not be compared to each other, and data for one county or one site will not be released independently.

While no one county's benefits will be spotlighted by being part of the National Children's Study, your county will be contributing to this future of America's health. Families in your county will be participating in this landmark study, which will enable you to learn more about the health of your community as well as the health and development of our children throughout America. The study will be bringing state-of-the-art resources to the community in order to analyze participants and their environment.

A great deal of effort has been given to determining who is included in the Study, what kinds of individuals and from what kinds of locations, and for reasons that are too complex to go into great detail here, let me say that it is important that we understand the environments of the communities in which the children are born and raised. It is therefore necessary, in order to do that, to have a series of communities throughout the country rather than a widely-dispersed sample, and for that reason a number of counties were selected as opposed to the participants being scattered widely across all counties in the country.

It is important that the exposures and outcome relationships identified in this study, which are the primary concerns of the Study, be representative of the U.S. population, and it's important that we observe—and because the exposures are very varied, in order to collect information about these highly varied exposures, the best way to do that and to have the exposure-outcome relationship representative of the U.S. population, a national probability sample is the appropriate approach that has been decided to be used for this study.

To tell you more specifically about how that sample was collected, Jim Quackenboss, who is on the phone, and who, from the Program Office, led our sampling approach, will share a few of these details with you. Jim?

MR. QUACKENBOSS: Thank you, Peter.

Good morning and good afternoon too. I'm out on the West Coast or closer to the West Coast so I'll get to say good morning.

The sampling, the decision to select the Study as a national probability sample came after a great deal of deliberation within the Study and by bringing in experts from the scientific community.

What we decided on was the need to select this as a national probability sample. To do this, we started with the listing of more than 3,000 counties in the United States and then selected 96 locations chosen to represent characteristics of the United States in the Study.

Your location was included through the use of a probability sampling method that looked at several variables to ensure that the 100,000 children who are included in the National Children's

Study represent the face of all of America's children. The locations roughly correspond to counties, or in some cases clusters of smaller rural counties.

In addition to population size, variables for location selection included the geographic region, which are the Census regions and divisions, demographic variables such as racial and ethnic makeup of the counties, and the percentage of babies born at low birth weight.

Using this information, a sampling statistician at the National Center for Health Statistics drew a sample of counties to allow us to then focus on these areas in terms of conducting the Study. Although not every county or even every state is represented among the locations, everyone will benefit from the National Children's Study. The findings from the Study can be applied to the health and environmental issues anywhere in the country.

With that, I'm going to turn over the discussion to Sarah Keim on the Study timeline.

MS. KEIM: Thanks, Jim.

At the same time that we sent out the packet of information to you about the National Children's Study in mid November, we also posted requests for proposals for institutions to serve as our initial or vanguard study centers and also for our central coordinating center.

The procurement process for these is going on now, and so we're accepting proposals to take on those pieces of the Study with the award of those contracts to institutions and organizations planned for probably September 2005. The procurement is open to all organizations and institutions that can perform the work and have a demonstrated capability to work with communities.

[There are] eight potential vanguard locations open for proposals, and I refer you to our map of sites if you are unfamiliar with which locations are the vanguard locations. Of those open for proposals, the actual number of centers awarded will depend on our federal funds available, and it'll probably be something like three to five of the sites.

They'll actually be awarded next September. If you have questions about participating in these procurements, questions about the scope of work intended, our Study Plan or protocol, the sampling approach or the contracting process, I want to give you a name and phone number here of somebody you can call, and that person is Virginia DeSeau, and her last name is spelled D-e-s-e-a-u.

She's at 301-435-6947. 301-435-6947. Her name is Virginia DeSeau. She's happy to answer any questions about that.

So these vanguard locations will be the first to be implemented, and depending on funding, the remaining locations, to make up a total of 96, will be engaged on a rolling basis, so that all of our recruitment for the Study takes place within a 5-year window, between 2007 and 2011.

Upon award of these initial contracts, the vanguard centers will start working with us to prepare for recruitment in those few sites. That will happen between September 2005 and through 2006, and during that time also the vanguard centers will be expected to be working with community leaders and others to talk about the Study and think about what are the best approaches for implementing the Study in their particular location. So we're hoping that recruitment can begin in these first vanguard locations in early 2007.

We've had a few questions from counties about what their roles can be in the implementation of the Study, either in these first vanguard locations or in the locations that will follow after that, and so I want to give you some ideas of different ways, if you're interested in participating.

We know there are a lot of variety and capabilities and interest among counties across the United States. Some of you may be—probably all of you are understaffed and overworked. But some of you have expressed a lot of interest in maybe even submitting a proposal to operate the Study in your community while others feel like maybe that's something they're not necessarily interested in, and we want to let you know that there is no requirement on counties or anything like that.

We don't mean to impose any work on you but we do want to give you the opportunity and want to let you be one of the first to know about the Study.

So here are some ideas of things you may be interested in. First off, let me refer you, just to learn more about the Study, you can always go to our Web site, which again is www.nationalchildrensstudy.gov, and all the materials that we send out to you are available there in electronic form as well as others, and feel free to pass those on to colleagues and others in your area or nationwide.

We'll be putting together a lot more information over time, and if you're interested, you can sign up for our e-mail listserv through our Web site there. You just go to the Web site and there's a place to sign up for our listserv where we send out quarterly news updates. So if you just want to keep abreast of what's happening, that's a good way to do that.

For right now, if you have general questions about the Study that aren't necessarily related to the contract but just about the Study and its intent, you can feel free to give me a call.

Sarah Keim, K-e-i-m. My phone number is 301-594-9147. That's 301-594-9147.

If you're interested in being an information resource for others in your community I can also, you know, provide you with materials, brochures, anything like that, that if you're interested in doing that.

One of the things we think is really important is that we have a very strong community engagement component for the Study, and given the length and breadth of the Study, we think that will be essential to its success, and communities need to be aware and engaged in the process right away. So you are invited to assist with that, if that is an interest of yours.

We expect that in the end, the Study will end up including all levels of government, federal, state and local. We've also been informing some of your counterparts at the state level about the selection of counties in their state. Schools and universities, hospitals, nonprofit institutions, private industry and foundations, and the medical and research community are already playing a part in this study. And so it's a very interesting and diverse group of people who are interested in its implementation. So we invite you to join that group.

We have already seen press reports in some of your communities where the media has been interested in writing about this study, coming to their county, and we even had a couple of counties we saw put out press releases about their selection as a National Children's Study location, and we welcome that kind of outreach. That helps us get the word out to potential participants, early on, and we can be a resource as well in terms of how to go about that.

If you feel like you would like some more information to be equipped to deal with the media, we are happy to assist with that.

We again don't want to make this difficult for you at all. We want to provide you any information and help that we can.

So while we are in the middle of this request for proposal procurement process for the initial study centers, if you think there are institutions in your region that should be submitting a proposal to be a Study site, please encourage them to do so. The documents for how to do that are posted at the following Web site. It's www.fedbizopps, and that's spelled f-e-d-b-i-z-o-p--p-s.gov. That's www.fedbizopps.gov.

And if you look up the National Children's Study, [there are] all the instructions you need for submitting a proposal.

Now I believe it's time that we can open up the line for questions.

MODERATOR: ladies and gentlemen, if you have a question or a comment at this time, please press the one key on your touchtone telephone. If your question has been answered and you wish to remove yourself from the queue, please press the pound key.

There are no questions at this time.

[Pause.]

MODERATOR: Oh, actually, we do have one question. Jane Duncan of Cumberland County.

QUESTION: Yes. I'd like to ask how we would get more information to distribute throughout the communities within our county, for example, to submit to newspapers or other organizations.

MS. KEIM: That's great. Well, our Web site is probably the easiest place to get that information, nationalchildrensstudy.gov.

But I can be a resource as well if you'd like to give me a call. I'm Sarah Keim, 301-594-9147, and we can talk a little bit more about what kinds of things you might think would work well for whatever audiences you'd like to get to, inform about the Study. So we'd be happy to do that.

QUESTION: Thank you.

MS. KEIM: We have some brochures, we have samples, press release materials, all kinds of things.

QUESTION: That's great; thank you.

MODERATOR: Our next question comes from Pam Hansen from New Haven Health Department.

QUESTION: Just looking at the Study locations, the vanguard locations, I see that New York City is the northeast location. It's confusing to me. So they're going to do the initial planning of how to get these, identify people throughout the—let's say in this example, the northeast?

DR. SCHEIDT: This is Peter Scheidt and let me answer that. A great deal of the planning is already done and a great deal more is underway, and it's not just being planned by the investigators at those initial centers.

There is an extensive sort of network of planning that includes a federally chartered national advisory committee, and its subcommittees and working groups, and an interagency coordinating committee of federal scientists, senior federal scientists in the agencies that are sponsoring this study.

However, when a study of this size is undertaken, it needs to start incrementally, with a small number of centers, to begin with, to test the feasibility, to work out the bugs, and with those centers and with the coordinating center, the final details of the protocol will be planned. But [it will be planned] with input from a variety of sources, including mechanisms for input from the interested groups, advocacy groups and potential future study sites.

The initial vanguard sites were selected with a method that intentionally was the same method that was used to pick the 96 sites from the over 300 counties around the country. Just as the 96 sites need to represent the United States, the vanguard sites needed to represent what those 96 sites look like. And the same method was used in order that we understand the kinds of challenges that the entire 96 study sites would have.

But the centers that will be involved in the initial phase with the vanguard sites will have a role of testing the feasibility and inputting into the preparations of the final details of the protocol and the Study manual.

So I hope that answers your question. Let me stop with that and see if you have any other details.

QUESTION: It did answer a large part of the question. It's not so clear to me how the other Study locations roll out from the initial Study locations, but it sounds like it's an RFP process as well.

DR. SCHEIDT: Yes, it would be; yes.

QUESTION: Some time in, I don't know, 2007, perhaps?

DR. SCHEIDT: Correct. That's exactly what we anticipate.

QUESTION: And then it's based on all of the initial work that they will be doing at the vanguard locations; correct?

DR. SCHEIDT: Well, that certainly will be informative and we will learn from that, you know, any changes, refinements, and further development of the protocol.

QUESTION: And just one last thought. Is the best way to get information as this thing rolls out, would be through the listserv?

DR. SCHEIDT: There are several ways. We would urge that you sign up on the listserv, what we call the Study Assembly, and we do produce regular updates, at least quarterly, with periodic updates about special news and events or developments in between. So that's the starting place. Then, if you have additional questions through the very same mechanisms that Sarah mentioned, e-mail to the Program Office, ncs@mail.nih.gov. And/or just call us with questions.

QUESTION: Okay. Thank you very much.

DR. SCHEIDT: You're welcome.

MODERATOR: Our next question comes from Frederick Kesslar of Grand Traverse City. You may ask your question, Frederick.

QUESTION: Our question is that as this process starts, how are the 100,000 women that are pregnant going to be solicited to participate?

MR. QUACKENBOSS: Do you want me to take that one?

DR. SCHEIDT: Yes, Jim; go ahead.

MR. QUACKENBOSS: Okay. Starting with the sample of 96 locations, within each of those locations we're going to need to try and define communities or segments within the county or set of counties, especially for the larger ones.

The target is to have approximately 250 births per year enrolled into the Study. For the vanguard centers, that will be done over a 5-year period, and for the remaining centers, we anticipate a 4-year period of enrollment.

And [for] those segments, we're hoping to use local input to help define boundaries that are appropriate in defining a community rather than relying entirely on Census information or information that we might have available.

Once we've selected a subsample of the communities, then the plan is to rely primarily on selection of households through, you know, traditional sampling methods, of obtaining a roster of households, either going out and doing a count-and-list type operation or from existing listings, to take a sample or to take all households within the community, and then contact people in terms of identifying those households that would have women that are eligible in terms of their ages and then asking them to participate in the enrollment period. Those women would then be broken into groups depending on their current likelihood of becoming pregnant. And for those that are at a higher probability of pregnancy, we would follow [them] more intensely in terms of trying to obtain some early pregnancy measures.

Does that help to answer your question?

QUESTIONER: Yes. We were just wondering if [inaudible - static].

DR. SCHEIDT: We missed that. Could you repeat that comment again?

QUESTIONER: I just said that we were just curious if both public health departments and private providers, if they would be helping recruit women who are presently pregnant or about to be, [or] planning to be.

DR. SCHEIDT: We think so. There are multiple approaches that will be used. Approaching the women for an initial contact of households and then, as the Study goes forward, to both catch those women that were missed by that approach and, as women move into the age group or decide that they are going to have a child or become pregnant, recruiting through contact with the obstetric care providers; and also just through promotion of the Study and awareness of the Study through the communities and public awareness of the communities as well—and whatever other approaches the communities may suggest or find effective. So any and all of those will be important. And the public health departments are engaged in maternal and child health programs from a variety of perspectives, and through those contacts and programs input to the National Children's Study would be enormously helpful.

OPERATOR: Our next question comes from Yolanda Brown from Orange County Government.

DR. SCHEIDT: Orange County—which Orange County?

QUESTIONER: Orange County, Florida. I'll ask the question. Larry Jones, with Orange County Government.

A group of us sitting around the table, we see Orange County selected as a vanguard site, which is fine; we have a lot of pinnacles in the community who would be eager to work with you. But we're wondering how the selection was made, and who do you anticipate being the lead agency on this project at the local level?

DR. SCHEIDT: As you heard Jim Quackenboss describe it, this was a probability sample from the 96 counties. So Orange County was one of the 96 that was selected as part of the national probability sample. And then, using the same process—stratifying by region of the country, by size of the community, number of deliveries, and certain sociodemographic characteristics, especially race and ethnicity—and then from each of those strata, counties were picked as a random selection to become the vanguard sites and thereby representing the entire 96 of the regional sites.

Nonetheless, the characteristics of Orange County are enormously important for what it represents of the 96 total Study sites, just as every one of those are important as representatives of the entire U.S. sample. And we then—you may be interested—pooled all of the counties that were selected and compared the pooled demographic and other characteristics of those counties and compared them to the entire United States, and they matched. So we know that they do in fact represent the entire United States, and each one of those is very important for its portion of that representativeness.

The centers to actually carry out the Study in Orange County could be a variety of institutions. They could be academic medical centers. They could be a strong county hospital. They could be a strong county health department. They would need to have the breadth of experience and capability to carry out the work, and we anticipate that a number will be academic medical centers, but, of necessity, those centers would need to work closely with the county health agencies and resources in the counties where the Study will be conducted. So that's the breadth of kinds of institutions that we think may be serving as Study centers.

OPERATOR: Our next question comes from Ulysses Ratehra of the Department of Human Services.

DR. SCHEIDT: Department of Human Services where?

QUESTIONER: [Off microphone, inaudible.]

DR. SCHEIDT: I'm sorry, we can't hear you. Is it possible to speak a little closer?

QUESTIONER: Sure. My name Ulysses Ratehra and I'm with the Department of Human Services in Miami-Dade County, Refugee Services Division. Can you hear me now?

DR. SCHEIDT: Yes, faintly.

QUESTIONER: I have a couple of questions. I want to change to those 96 sites that were already selected. I was just wondering—I'm not familiar with the Study; this is the first time I heard about it. I have not seen any written information or accessed any of the Web sites. I will eventually, but at this point I was basically interested in finding out if Miami-Dade County had been selected as one of those 96 sites due to the diverse characteristics of this county and the continued influx of refugees in this community. As you said, Orange County has very important characteristics in the population, but they're totally different than the ones from Miami-Dade County. So I was just wondering if any consideration had been given to selecting Miami-Dade County as one of those 96 sites.

DR. SCHEIDT: The answer is yes. Miami-Dade County has been selected as one of the 96 sites. It was selected using the process that we described as a probability sample. And it is different from—it has its own unique characteristics. But because of those unique characteristics, it is important as part of the overall sample for the United States.

So I think that answers your question about whether it was selected or not. It was selected using the sampling process and within the strata, or the groups based on the characteristics I mentioned, that selection process was random.

QUESTIONER: I do have another question. I understand, as you said at the very beginning of this conversation, that this is a very ambitious project and it needs to be supported through 2011. In the RFP process, I think my understanding was that you are only going to be selecting a few sites for the Study. So my question is, being totally unaware of the scope of service that is involved or any of that, what is the dollar amount that is available through this RFP process for those entities that are interested in participating in [inaudible]?

MS. KEIM: That's a good question. As I mentioned, we do plan to be able to institute just a few of the vanguard sites during this fiscal year, which is now through next September. We have, from our federal budget, approximately $12 million available to do all of our study activities this fiscal year. We don't yet know how much actually will go into each of those vanguard sites. It depends on how many we award this fiscal year. The remaining sites will be instituted after that time based on funds availability. We're optimistic that we'll be able to do that, but of course it does depend on our federal appropriations which we get from Congress every year, year by year. We've projected out that to be able to carry out the Study on the timeline that we currently have, our funding need for fiscal year 2006 is approximately $69 million, so some of that is for the state center, some of that is for our coordinating center, some of our other infrastructure activities and pilot studies. So if that gives you a sense.

I did want to mention that if folks in Florida are interested, as Peter mentioned, Dade County and Orange County, obviously, are two of our sites in Florida, but Baker County and Hillsboro County in Florida are two of our other study locations. Those are the four that we have in Florida.

QUESTIONER: Of course this has a tremendous benefit [inaudible] study, and while you're collecting data from the [inaudible] that are being selected for the Study, what would be the

Phase 2 of this project? I mean I know you're piloting this, but after that, after you have collected the data from the sample, what would be the Phase 2 to kind of create awareness on education based on the findings of the Study? What is the strategy that is going to be used for that?

MS. KEIM: We expect to be collecting data from, as you mentioned, from before birth through age 21 on a sort of continuing basis, and our effort is to try to get the results from that data collection and analysis out as soon as possible, as soon as we can as the Study goes along. We're not going to, you know, hold all the data till the end and then analyze it. We'd like to be able to get results out there as soon as possible, publish them in the scientific literature and offer them up through our communications with our participants and communities, through things like newsletters and Web sites and different materials like that so that they have good information back on what the Study is finding.

Our mission is to institute the National Children's Study. We are very much an interagency project at the federal level between the National Institutes of Health, the Environmental Protection Agency, and the Centers for Disease Control and Prevention. So we are connected up with a lot of prevention programs and other health-related programs across the federal government that we hope can use the results from the Study to institute programs.

We also are hopeful that that happens at the state and local levels too, so we are looking to make plans to do that. We're just now trying to get the Study launched.

DR. SCHEIDT: A good example of that might be seen in the recent experience with the Women's Health Initiative. Results from the Women's Health Initiative, in fact, and the findings that they provided about the use of supplemental estrogens in postmenopausal women, just by announcing those important findings, have dramatically changed the use of those medications in postmenopausal women in this country, and various organizations and entities in the news have used this to expand—to make this both practice and policy change.

We expect similar kinds of uses of information from the National Children's Study about how exposures in pregnancy may result in differences in pre-term birth and in child neuro-cognitive development and similar, with regard to exposures in relation to asthma, to obesity, to mental health, et cetera. And I think that is an example of how the kinds of information from the National Children's Study can result in both policy and care benefits to children in those areas.

Other questions?

OPERATOR: Our next question comes from Elaine Moss of Dupage Public Health.

QUESTIONER: Elaine Moss from Dupage County Human Services in Wheaton, Illinois, and that's Dupage County.

One of the questions that I have, or several questions that I have, there continues to be talk about diversity. How do you plan to continue to have that diversity? And then also one of the things I

know, or maybe you can correct me on this, Dupage County is a very diverse community. We have a lot of individuals from very diverse backgrounds, speak different languages. How do you plan on getting those individuals involved? And also, are there any plans to get individuals that you're sampling involved in the Study?

DR. SCHEIDT: I'm not sure. Let me just ask for a clarification on that. You mentioned how do we plan to get individuals that we're sampling involved. The individuals that we're sampling will be recruited into the Study and will be followed with periodic visits, calls, information, data collection, samples collected, both environmental samples in their home environment, and blood samples, et cetera. That's how the—is that what you meant?

QUESTIONER: Yes, that is correct, sir. That is correct. Thank you.

DR. SCHEIDT: But about the diversity. We're very concerned about the issues of diversity, and that the diverse components of our society and the various race and ethnicity groups be represented in the Study. And in fact, in the planning process, we paid careful attention to this, and had special working groups actually focused on health disparities and those issues. When necessary, to capture the diversity of the population in the Study sites, we will oversample to assure that the important subpopulations are included in the sample. And that will happen at the--what we call the secondary sampling stage. We've just described to you the primary sampling stage, which is the selection of the counties. Within the sites or counties, the individuals—the segments that Jim Quackenboss described to you—will be selected in ways to assure that important subpopulations will be included, that represent the composition of each of the counties.

In some areas there's ample representation. If there's a county that's 50 percent African-American, 50 percent white, that's fine. Other places there may be 10 percent Asian, and it may be necessary to oversample that in order to have enough in that group, and the same with African-American and other populations. So attention will be paid to those issues at the secondary sampling stage at the site levels.

QUESTIONER: Thank you very much.

OPERATOR: Our next question comes from Sadia Lunsford of Harris County. You may ask your question, Sadia.

QUESTIONER: This is Sadia.

MS. KEIM: Where did you say you were from?

QUESTIONER: From Harris County.

MS. KEIM: Harris County, Texas?

QUESTIONER: Yes, ma'am. I have a question. Can more than two institutions located in the same county participate in the Study? Did you hear me?

DR. SCHEIDT: Yes. I'm sorry. Your question was can more than two institutions in the same county participate?

QUESTIONER: Yes.

DR. SCHEIDT: In the Study as centers to carry out the Study?

QUESTIONER: Yes.

DR. SCHEIDT: We can only award one contract for a specific center. The way two centers can participate would be by joining together as a partnership or some similar arrangement. And we in fact are encouraging those kinds of arrangements. We think the more of that that is undertaken, the more successful and the greater the reach of the Study will be.

But we won't be awarding contracts to multiple institutions to carry out the work within the same site. They're going to have to cooperate to do that. Does that make sense?

QUESTIONER: Yes, thank you.

OPERATOR: Our last question comes from Ardine Butrow of Department of Human Services.

QUESTIONER: We want to find out what are the incentives for families who will be participating in this study?

MS. SHREEVE: What county did you say you were from?

QUESTIONER: Miami-Dade County.

MS. SHREEVE: Okay.

DR. SCHEIDT: There will be several kinds of incentives. At first, as with many of these kinds of studies, we will be providing financial compensation for the inconvenience and the effect of participating in the Study. We anticipate providing reimbursement for expenses such as travel and child care, and in addition, an appropriate amount of money to compensate for the inconvenience, not so much that it isn't an excessive inducement, but enough that's appropriate and an incentive, and there are guidelines for that within the research ethics communities.

In addition, of course there is the incentive of contributing to probably the most important study of children's health and development that's ever been conducted in this country, and making that contribution to understanding the important aspects of our children's environments and their health.

But finally, we think the most important incentive for participating is what the families and parents will learn about their children and their children's environment and health.

We will be collecting a great deal of information about the environment and about the children, and as they grow, their development. And we'll be doing fairly sophisticated developmental measures, physical growth assessments, and assessments of their environment. And this information, as we learn it, will be made available to the participants in the Study, and so they'll be able to learn about how their children develop and how they develop in comparison to norms, and when appropriate, and when there are abnormal conditions identified, they will be informed of this, and the appropriate health care providers and resources will also be informed.

Our experience with the Women's Health Initiative has been that that factor of learning about their health through the various procedures of the study, the investigators of the Women's Health Initiative tell us, is in fact what those participants in that study have valued the most, and we think the children in this study with much more information, will benefit considerably from this important information. Does that help?

QUESTIONER: Very much, thank you.

OPERATOR: There are no further questions at this time.

MS. SHREEVE: Can we hold for just a second and see if anyone wants to ask any follow-up questions?

OPERATOR: Sure.

[Pause.]

MS. SHREEVE: Okay. If there are no further questions, I want to thank you all for participating today, and we really do appreciate your time and interest. I know you're all very, very busy, and we are happy you took an hour out of your time to come hear more about the Study.

We're excited to have you with us and—

OPERATOR: Pardon me, Ms. Shreeve. There is one more question.

MS. SHREEVE: Go ahead.

QUESTIONER: —with Waukesha County and we have a group around a table here. I will ask some of my pragmatic questions, and we have a county supervisor who would like to ask a few questions.

One of the things that I can see up front is that there is a tremendous amount of tax funding that would be invested in this, but I see in the long term that if we prevent these postnatal issues in

children, we will probably save taxpayers an enormous amount of money, but that's just my researcher heart.

One of the things, the university that would be awarded the RFP, will they be establishing the community advisory committees?

MS. KEIM: I'll take that question. It may not be a university that receives the contract, but certainly universities and all other institutions are welcome to apply. Whoever is awarded the contract is expected to take a leading role in establishing a mechanism that fits the needs of their community and the needs of the research project there in the Study center to get the community input that's going to be so valuable and important. So it may be a community advisory board. It may be a slightly different mechanism. We'd like to leave that a little bit flexible so that they can do something that is tailored to their community.

QUESTIONER: I guess I was thinking institution. But my thoughts are that whatever institution gets the RFP, would they take us then through their use of human subjects board? Are you supplying information on that, on use of human subjects?

DR. SCHEIDT: I'll take that. This is Peter. This study will be reviewed by the human subjects board, what's called the IRB, at NIH, and we anticipate from that to be able to provide guidance and help the reviews at the local sites, as much as possible. But we also anticipate that local sites will have to review the Study as well locally, and that we hope that the information that we provided—the review that's provided at the NIH level will be helpful to those local boards, so that they can do that as knowledgeably and as efficiently as possible. But we do anticipate that all of the local sites will have to also conduct their own reviews.

QUESTIONER: And my last question really is an ethics one. This has to do with going through health care providers. Part of your proposal is to measure placental size and obtain placental blood. You think that might be an issue at all with some of the major medical centers that participate in the deliveries?

DR. SCHEIDT: By an issue you mean the procedures to collect those specimens?

QUESTIONER: Yeah. I know the subjects have to approve consensually.

DR. SCHEIDT: Yes, they would.

QUESTIONER: I'm just wondering how you worked that out with the hospitals.

DR. SCHEIDT: Yes. There are a variety of approaches to doing this. Some hospitals may have procedures that will make it—allow it to be fairly efficient to collect and provide specimens of placentas. For others it may be more difficult, and it might even be necessary for the Study centers themselves to provide the staff to be available at delivery to collect not only the placenta tissue but the core blood samples and other data about delivery and from the mother.

And we did not prejudge. We've considered and discussed in considerable detail, and in fact, have gone through site visits at hospitals to be sure that we understood the different challenges that we're faced with this, but we did not prejudge how a site can best do this, and felt that this is a level of detail that might be worked out different ways in different sites, and we wanted to leave it open for sites to propose the most efficient procedures to collect placental tissue and similar types of specimens at the local site, and we're prepared to provide guidance in that as necessary once the vanguard centers get started.

QUESTIONER: Thank you. My last question then is—I'm sure this will come at a later date—but what the directives would be with the community partners in terms of recruitment of subjects. My thoughts are the public health departments have a skewed population, and we would need to enlist a broader group of health care providers that have a broader population, and that is my last question.

And then our trustee, Cal Hamm, will be asking some.

DR. SCHEIDT: The sample from the segments or the portions of the county need to reflect the face of that county, just like the Study, the 96 sites around the country need to be representative of the United States. And so it's important that that be, as much as possible, representative of Waukesha County for Waukesha. And so the steps need to be undertaken in the planning of the sample for Waukesha County to include the diversity and the distribution of the population that is really representative.

And so the Study center that carries out the Study in Waukesha County will need to work with all of those components that the health department, providers and other components of the county, in order to assure that the sample is reflective of Waukesha County.

I can't, without actually going further into details of Waukesha County, be any more prescriptive than that, except to say that those are challenges for not just Waukesha County but every county.

QUESTIONER: Thank you. This is Supervisor Andy Callan on the line now, and I do have a couple of questions for you as well. Kind of following up, first of all, on the financial aspect of this, we're looking at following roughly 1,000 women per year to get 250 pregnancies. We're looking at committing our resources for 30 years as a county in some form. I mean even if some other center takes on as the resource center, we still will be committing our county funds to this.

No. 1, if we do participate and funds for this study dry up in the future, can we opt out at that point, or can we opt out at this point?

The second question that I have involves the material and data that you are looking to develop and gather on these people. The PATRIOT Act has a lot of people concerned with the giving up of freedoms and rights, and we're looking now to have people voluntarily give up not only their genetic data for the parents, but also committing their children, unborn children to the same type of scrutiny. What type of programs are we looking at as far as safeguards, and is this going to be as invasive as it seems to me to be?

DR. SCHEIDT: Let me try the opt out one first. This study is a volunteer study, both on behalf of the participants—participants will be asked to participate, will give their consent to participate, but that is always volunteering and participants always have the option to cease to continue participating. We hope they won't and we hope that it'll be important enough to them and beneficial enough to them, that it's in their interest to continue.

But there is nothing obligatory on the part of the participants or on the part of those entities carrying out the Study to continue when it's not in their interest.

We think that the Study is enormously important and to the benefit of the participants and the industries and the jurisdictions where it'll be carried out, and that it would be in all of your interests to continue. But there's always the ability to opt out.

With regard to the risks that participants may take, most especially by providing information about themselves, especially their genetic information to this study, we are very cognizant and aware of this challenging problem. There are a wide range of procedures that are used to assure as much as humanly possible that the confidentiality of providing this information will not be betrayed, and they include anonymizing the information, you know, to any of those potential users of the information.

Of reconsenting and assenting the participants, so that when the children in this study reach an age where they understand what it means to be participating in this study, in order to use their information and to continue to gather information, it'll be incumbent on us to seek their assent, and then to, you know, require that they give us their consent in order to use their information.

There was an ethics working group involved in the planning of this study. The advisory committee was very concerned about the ethics of the Study. We have a senior, very experienced bioethicist of national stature with us full time in the Program Office, attending to the human subjects and consent concerns, and a subcommittee of the advisory committee will be dedicated to the ethics of this study, to assure that the mechanisms for the protection of human subjects and their potential risks will be carried out, and I could go on and on but I think that's a quick overview.

QUESTION: Okay. I do have a quick follow-up if I may.

MS. KEIM: Can I clarify something about one of your original questions about the financing. Counties aren't being asked to contribute any of their own funds to carry out the Study. The funds are expected to come from the federal level to the institution to our contractor to carry out the Study. I mean, if you decide in your county you'd like to dedicate staff time or anything to working on the Study, that's, you know, up to you. But we're not asking counties to help us fund this or anything of that nature.

So I hope that clarifies that point, if that was part of your question.

QUESTION: That does help clarify that portion as well. I do have one follow-up on this whole situation here. You said that you would want this information to be valuable to everybody and that you would hope that people would continue in the project to get better data on themselves, and if you're not going to share and release to us our local information so we have something as a comparison, or if, say, somebody's genetics come back that there's a problem and you're not going to share back that information to the individual, what exactly are you looking at on the individual or county level, that this is going to be a benefit to them?

DR. SCHEIDT: On the individual level, we anticipate sharing information that we gather, that informs us of any known risks that participants have, that we discover as a result of conducting this study.

Examples of that might be if there's an elevated lead level, a blood lead level in a participant, and we collect that and we anticipate measuring it, and providing that information in a timely manner, if it's elevated to the participant, so that further risk can be avoided.

That kind of feedback is anticipated. Where we learn of, let's say, clusters of risk that are important to a community, that the health department may not be aware of, that become apparent through this study, we think we have an obligation to share this with a community.

We do not anticipate providing broad measures of community characteristics, by community, to the entire study, so that all communities can compare other communities with themselves. We may provide information about a community to that community, and then the same information combined for the entire sample. So a community can understand how they might measure with regard to the entire sample but not to other specific communities, because we really don't think that's fair, to be providing information about one community to another.

I could go further but I think I'll stop with that and see if that helps you understand what, helps answer the question.

QUESTION: Thank you.

DR. SCHEIDT: With regard to—you mentioned genetic information.

[Simultaneous conversation.]

DR. SCHEIDT: Genetic information will require special attention and caution, and we will provide that information with guidance from ethical review and ethics advisory committees, about just what genetic information to provide back to participants. But if it's important for their health, we anticipate being able to provide it to them.

Any other questions or clarifications?

MODERATOR: There are no further questions at this time.

MS. KEIM: Well, thank you again, everyone, for taking the time to participate.

Our hope and expectation is that the National Children's Study will help make dramatic improvements in children's health and greatly improve our understanding of the role of the environment in their health.

We're excited to have you with us as we embark on this endeavor and we look forward to speaking with you further. Please, again, if you have any questions or would like any additional information, here is our contact information again.

Our phone number is 301-594-9147. Our e-mail address is ncs@mail.nih.gov, and our Web site is www.nationalchildrensstudy.gov. You may be wondering when you'll next hear from us or you may be wondering when you'll know when something is starting up in your community, and subscribing to our e-mail listserv is an excellent way to hear about those kinds of things. All those pieces of information and news are posted there and [in] our e-mail newsletters. So again thank you, and have a great week and a great holiday.

MODERATOR: Ladies and gentlemen, this concludes today's presentation. You may now disconnect.